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| 10/608,520 | 06/27/2003 | Matthias Gerlach | 103832-506-NP | 8727 |

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GOODWIN PROCTER L.L.P.
599 LEXINGTON AVE.
NEW YORK, NY 10022

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| EXAMINER |
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WARD, PAUL V

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| ART UNIT | PAPER NUMBER |
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1624

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06/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/608,520 | Applicant(s) GERLACH ET AL. | |
| | Examiner PAUL V. WARD | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12, 13 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-16 and 20 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II_f in the reply filed on March 12, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant is entitled to have the method claims or the process of making claims (Group V-VIII and IX-XII), which are commensurate in scope with the elected invention, rejoined, if the compounds in Group II_f are allowed. An amendment, which results in the method claims and process of making claims being commensurate in scope with the allowed claims, will be welcomed.

Groups I, and II_{a-e}, III-XII are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant reserved the right to file a divisional application to the non-elected subject matter.

An action on the merits of Group II_f (claims 1-11, 14-16 and 20) is contained herein.

Claim Objections

1. In Claim 1, Examiner suggests that Applicant replace the phrase "where the substituents have the following meaning" with the term "wherein".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

The claim is directed to a pharmaceutical composition or compositions comprising the claimed compounds. The claims are rejected for lack of enablement because there is an insufficient teaching of how to use the claimed compositions as claimed. The term "pharmaceutical composition" specifies that at least some therapeutic benefit arise from some property of the composition. However, Applicant has not taught how to use the compounds of the invention to therapeutic effect for any condition.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to solvates. But the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was

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stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190, "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However...there is no evidence that such compounds exist...the examples of the '881 patent to not produce the postulated compounds...there is...no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-11, 15-16 and 20, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1-11 contain quotation marks (e.g., "---") throughout the claims.

Correction is required in all instances.

6. Regarding claim 2, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d). Examiner suggests, for example, using the language "...a halogen selected from the group consisting of....". Correction is required.

7. Claims 3 and 4 are indefinite because it reads "in claims 1" and "in claims 2".

Correction is required.

Claims 1, 9, 15, 16 and 20 contain the term "tolerable", which is a relative term rendering the claim indefinite. The term "tolerable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Examiner suggests deleting the term "tolerable" from the claims.

8. Claim 11 does not end in a period. Correction is required.

Claim Rejections - 35 USC § 102

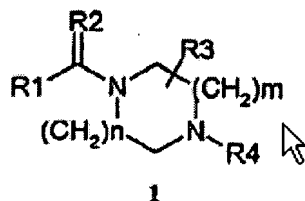
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-11, 15-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ermandi et al. (Farmaco Ed. Sci.).

Applicant discloses aryl and hetero arylcarbonyl piperazine compounds with a general formula:



wherein all the variables are as defined in the claim.

Ermandi teaches aryl and hetero arylcarbonyl piperazines, which share the same formulaic compounds. (See formula 1, page 519). The compounds in the said

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reference has the same structure, which includes n as 1, R₁ is 1-H-pyrazole, R₂ as O, R₃ as H, alkyl or halogen, R₄ aryl or heteroaryl, and falls within the range of Applicant's compounds. (See pages 519-21). Since Ermandi teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

10. Claims 1-11, 15-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al. (WO 01/19798).

Zhu teaches aryl and hetero arylcarbonyl piperazines, which share the same formulaic compounds. (See formula 1, page 11). The compounds in the said reference has the same structure, which includes n as 1, R₁ is 1-H-pyrazole, R₂ as O, R₃ as H, alkyl or halogen, R₄ aryl or heteroaryl, and falls within the range of Applicant's compounds. (See pages 11-32, Tables 1-7, and examples 1-123). Since Zhu teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-11, 15-16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al. (WO 01/19798).

Zhu teaches a generic group of aryl and hetero arylcarbonyl piperazine derivatives, which embraces Applicants' claimed compounds. (See formula 1, page 11,

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and definitions for A, Q, D, E, G, J, and X). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

Conclusion


Claims 1-11 and 14-17 and 20 are pending. Claims 1-11 and 14-17 and 20 are rejected. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James Wilson
Supervisory Patent Examiner,
Technology Center 1600